# Exhibit A

REDACTED

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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|---|---|
| IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION | **No. 1:19-md-2875-RBK** |

# EXPERT REPORT OF KALI PANAGOS, PHARM.D., RPH.

**Expert Declaration of Kali Panagos, Pharm.D., RPh.**

## I. Introduction

1. I have been asked to render an opinion regarding the type of information third party payors ("TPPs") rely on and consider when selecting generic drugs for inclusion on their formularies and subsequently paying for generic drugs and, more specifically, the generic Valsartan and Valsartan Containing Drugs at issue in this litigation.

2. The opinions I provide in this report are expressed with a reasonable degree of certainty based on my expertise and the information I have reviewed and been provided to date.

3. In the context of my preparation of this report, I reviewed the materials which are listed and identified on Appendix A.

## II. Qualifications and Experience

4. I have earned two Bachelor of Science degrees from St. John's University in New York; a Bachelor of Science degree in Biology with a minor in Computer Science as well as a Bachelor of Science degree in Pharmacy. I completed my Doctorate degree in Pharmacy (Pharm.D.) from Shenandoah University Bernard J. Dunn College of Pharmacy, Winchester, Virginia.

5. I am a registered pharmacist (R.Ph.) in the state of New York.

6. My clinical affiliations include a focus on pain management/anesthesia at The Hospital for Special Surgery, cardiovascular and lipid focus at Bellevue Hospital, and internal medicine at Northwell Health, all in New York City.

7. I currently serve as EVP (Executive Vice President) of ARMSRx Pharmacy Benefit Consulting, a nationally recognized consulting firm dedicated to providing pharmacy benefit guidance to self-insured employers, health plans, brokers and TPAs/TPPs. I have over 20 years of pharmacy experience, more than half of which has been dedicated to the managed care and pharmacy consulting industry overseeing clinical development, pharmacy benefit strategies, and overall Pharmacy Benefit Management (PBM) operations and client services/management working primarily with self-insured clients, third-party administrators ("TPAs") and TPPs.

8. I am an industry expert speaker at national industry conferences where I speak about managed care drug strategies and medications.

9. I have served on the faculty and administration of Long Island University's ("LIU") Arnold & Marie Schwartz College of Pharmacy in Brooklyn, New York. My roles at the LIU involved teaching within the pharmacy program, serving on curriculum and academic committees, and serving as the Director of the Pharmacy program, determining whether students meet the criteria to continue in the program and/or where gaps exist to assist students succeed. Presently, I also serve as an alumni mentor to upper-level pharmacy students, primarily those students interested in non-traditional and managed care career paths at St. John's University College of Pharmacy in New York.

10. I have also served with the New York State Board of Pharmacy as an examiner for the pharmacy compounding licensure examination.

11. A full and current copy of my CV can be found at Appendix B.

## III. Prior Testimony and Expert Opinions

12. I have neither been deposed nor testified in any legal proceeding as a fact witness or expert in the past four years, other than being deposed in the present litigation on January 21, 2022.

## IV. Pertinent Background on Valsartan

13. Diovan and Exforge (collectively, the "Reference Listed Drugs") are a class of medications known as Angiotensin Receptor Binders ("ARBs"). The FDA approved Diovan on August 3, 2005 and Exforge on June 20, 2007.

14. Valsartan and Valsartan containing drugs (collectively, "VCDs") are generics for the Reference Listed Drugs.

15. [redacted]

[redacted]

16. In July 2018 and September 2018 respectively, the FDA announced a voluntary recall of VCDs due to contaminants NDEA (N-Nitrosodiethylamine) and NDMA (N-nitrosodimethylamine). These contaminants are probable human carcinogens according to the International Agency for Research on Cancer (IARC) classification.[1] Subsequent recalls followed.

17. NDMA is classified as a group 2A carcinogen which means that it is probably carcinogenic to humans and there is sufficient evidence that it causes cancer in humans.

18. Animal studies have found that NDMA caused liver and lung cancer, as well as other cancers such as esophageal cancer, bladder cancer, gastric cancer, colorectal cancer and others.

19. NDEA, similar to NDMA, is also a probable human carcinogen as per IARC classification.

## V. Background on TPP Pharmacy Benefits

### a. TPPs

20. The term TPPs generally refers to entities (other than the patient or health care provider) that reimburse and manage healthcare expenses including prescription drug benefits or coverage. It is my understanding that the Court will conduct a trial which will involve purchases paid for by SummaCare, Inc. ("SummaCare") and EmblemHealth ("Emblem"), both of which are TPPs. These TPPs, as with most TPPs, both included generic VCDs on their drug formularies and reimbursed for purchases of these VCDs (intended for personal or household use). Many of these VCDs were manufactured, distributed, or sold by active pharmaceutical ingredient and finished dose manufacturers, including the relevant defendants here, Zhejiang Huahai Pharmaceuticals ("ZHP"), Teva Pharmaceuticals and Torrent Pharmaceuticals.

21. SummaCare and Emblem are the payors ultimately responsible, or at risk, for payments associated with their insureds' purchases. Consumers pay their portion (referred to as

[1] https://monographs.iarc.who.int/agents-classified-by-the-iarc/

a copay) and SummaCare and Emblem pay the remaining portion (also referred to as "plan paid").

22. TPPs manage claims processing, provider networks, utilization reviews, formulary, and membership.

23. The prescription drug pharmacy benefit represents eligible medications for reimbursement under the prescription drug benefit via the prescription formulary. The prescription drug benefit is different and apart from the medical benefit.

**b. PBMs**

24. A PBM is a third-party administrator contracted to administer prescription drug plans for a variety of sponsors including commercial health plans, self-insured employer plans, union plans, Medicare Part D plans, and federal and state employee plans.

25. TPPs can hire PBMs to provide prescription claims processing and other services. Examples of third parties that hire PBMs are insurance companies, employers, Medicare Part D prescription drug plans ("PDPs"), and state Medicaid programs. PBMs establish pharmacy networks as part of their claims management services, so many pharmacy third-party contracts are with PBMs. In addition to processing claims for prescriptions filled at pharmacies, other services PBMs provide include drug benefit design, formulary development and management.

26. PBMs negotiate discounts off the purchase price of prescription drugs and pass those savings on to the payor. The "payor" could be an insurance company, commercial health plan, self-insured employer plan, Medicare Part D plan, Federal Employee Health benefit program, or state government plan. I attach as **Exhibit A** a chart showing the role that PBMs play in managing drug benefits and the related flow of payments.

27. It is my understanding that Express Scripts provided PBM services to Emblem Health from January 1, 2012 through December 31, 2019 and that MedImpact provided PBM services to SummaCare from October 1, 2011 through December 31, 2018.

**c. Prescription Drug Formularies**

28. A prescription drug formulary is a list that specifies what drugs are covered under a medical plan and at what coverage amount. The primary function of a formulary is to provide

pharmacy care that is clinically sound and affordable for TPPs and their plan members and to help manage drug spend through the appropriate selection and use of drug therapy.

29. The typical development and management of the formulary occurs with the guidance of a Pharmacy & Therapeutic ("P&T") Committee or equivalent body. A P&T committee is an advisory body of experts from across the United States usually composed of health care professionals with broad clinical backgrounds and/or academic expertise regarding prescription drugs.[2]

30. PBMs typically have a P&T committee, as do may TPPs. Here, both EmblemHealth and SummaCare have their own internal P&T committees.

31. EmblemHealth's P&T committee is comprised of EmblemHealth network physicians of various specialties, pharmacists and administrators. The committee meets regularly and the drug formularies are updated regularly through formulary updates.

32. SummaCare's formulary and utilization management restrictions are developed, reviewed, and approved[3] by the SummaCare P&T Committee which is comprised of network physicians and pharmacists.

33. The majority of P&T members are actively practicing pharmacists and physicians. The Centers for Medicare and Medicaid Services ("CMS") also provides requirements for P&T committee composition. P&T committees are structured to provide non-biased, quality and evidence-based formulary decisions with the primary consideration being the clinical merit of the drug.

34. An example of P&T committee composition is as follows:

a. 4 pharmacists (1 academic, 1 hospital, 2 geriatric);

b. 18 physicians (representing broad specialties);

[2] In some cases, the development and management of a drug formulary is done "in-house" where the TPP will use its own P&T committee and might consult with the PBM. No matter which combination is used, the principles discussed herein are equally applicable.

[3] https://www.summacare.com/-/media/project/summacare/website/document-library/forms-and-resources/provider-forms-and-resources/provider-resources-provider-manual.pdf?la=en

c. Specialties represented: Allergy, Cardiology, Clinical pharmacology, Endocrinology, Family practice, Gastroenterology, Gerontology, Hematology/oncology, Internal medicine, Infectious disease, Pediatrics, Neurology, Medical ethics, Pharmacoeconomics, Pharmacology, Psychiatry, Rheumatology, Pharmacoeconomics, Pharmacology, Psychiatry, Rheumatology.

35. The P&T committee is required to base formulary decisions on scientific evidence, standards of practice, peer reviewed medical literature, accepted clinical practice guidelines and other appropriate information. All reviews are to be conducted from a purely clinical perspective involving U.S. Food and Drug Administration ("FDA") approved indications.

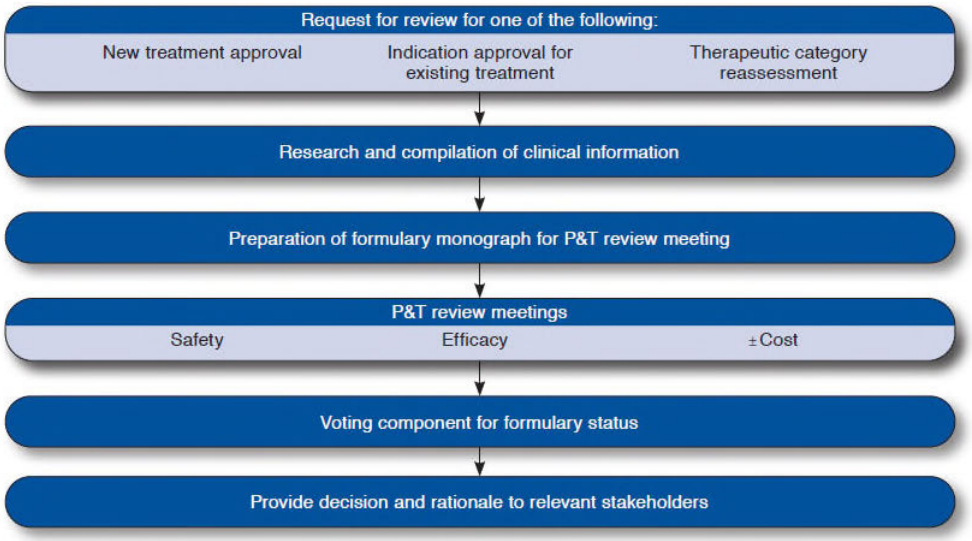
36. Typically, P&T committees meet on a quarterly basis and as needed to review issues that may arise which might impact the plan's formulary.

37. Members of a P&T committee are subject to completion of a "conflict of interest" disclosure form as well as a "non-disclosure" annual agreement.[4]

38. The below demonstrative[5] shows how the P&T committee typically makes decisions regarding its drug formularies:

[4] *E.g.,* https://www.caremark.com/portal/asset/FormDevMgmt.pdf

[5]https://www.jmcp.org/na101/home/literatum/publisher/jmcp/journals/content/jmcsp/2020/jmcp.2020.26.issue-1/jmcp.2020.26.1.48/20191226/images/medium/fig1.jpg




*P&T = pharmacy and therapeutics.*

## VI. ANDA Approval

39. An ANDA is a request to the Food and Drug Administration (FDA) to manufacture and market a generic drug in the United States.

40. Section 505(j) of the Federal Food, Drug and Cosmetic Act (FD&C) permits any person to submit to the Food and Drug Administration (FDA) an ANDA to seek approval to market a generic drug.

41. The applicant relies on the FDA's finding that a previously approved drug product, the RLD, is safe and effective and must demonstrate that the proposed generic drug is the same as the RLD, among other things.

42. The RLD is the specific listed drug on which the ANDA applicant relies in seeking approval of its ANDA, i.e., the approved drug product the proposed generic drug is intended to duplicate.

43. Regulations require an ANDA to contain a "basis for ANDA submission" (referred to as the basis of submission or BOS).

44. The RLD should be provided as the BOS on Form FDA 356h and in the appropriate sections of the ANDA (e.g. section 1.12.11).

45. An ANDA applicant must compare its proposed product and labeling to the RLD's formulation and inactive ingredients.

46. The supply chain must be solid and for approval of an ANDA, Good Manufacturing Practices[6] and inspection reports are considered.

## VII. ORANGE BOOK

47. The FDA created the Approved Drug Products with Therapeutic Equivalence Evaluations, known as the Orange Book, as guidance in creating formularies and to regulate substitution. The first edition appeared in October 1980; a new edition is published each year and cumulative supplements are made available on a monthly basis. Named for the orange cover of the book, it is now published in electronic form and accessible on the internet in an electronic format. The publication contains a list of all the drugs approved on the basis of safety and effectiveness by the FDA for marketing in the United States.

48. The Orange Book is an authoritative source of lists of generic drugs that are approved to be safe and effective substitutes for their referenced listed drugs ("RLDs") in the United States and it plays a critical role in the FDA's ability to implement the Hatch-Waxman Act.

49. The Orange Book lists drug products approved on the basis of safety and effectiveness by the FDA. The main criterion for inclusion of any product is that the product has a current, approved Abbreviated New Drug Application ("ANDA"). The Orange Book contains therapeutic equivalence evaluations for approved generic prescription drug products.

50. Generic drug manufacturers are permitted to avoid the expensive and lengthy New Drug Application ("NDA") process by filing an ANDA, when a generic drug contains the same active ingredient, route of administration, therapeutic equivalence, and other characteristics as the brand version.

51. The Orange Book consists of five main sections: an introduction, a "how to use" section, the drug product lists, appendices, and a patent and exclusivity information addendum. The drug product list consists of all approved drug products and their respective therapeutic equivalence codes.

[6] https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/abbreviated-new-drug-application-anda-forms-and-submission-requirements

52. The Orange Book lists generic drugs that are approved to be substitutes for corresponding listed drugs because they are safe and effective and the same as the listed drugs.

53. P&T committees will only consider adding a generic drug to their formulary if it is listed in the Orange Book and the Orange Book indicates the generic drug is the same as the RLD. As such, the Orange Book is an essential part of their decision-making process.

**a. Definitions and Significance of Therapeutic Equivalence Codes in the Orange Book**

54. The Orange Book has created a list of Therapeutic Equivalence ("TE") Codes. These codes are as follows:

a. *Pharmaceutical Equivalents ("PE"):* drug products which contain the same active ingredients in the same strength and dosage form delivered by the same route of administration.

b. *Bioequivalent Drug Products ("BE"):* drug products that have shown comparable bioavailability when studied under similar conditions (e.g. the rate and extent of absorption of the test drug does not significantly differ from the reference drug).

c. *TE = PE + BE for same use.*

55. These TE Codes are further divided into two categories, A-rated and B-rated.[7]

56. A-rated Drugs are those which the FDA considers to be therapeutically equivalent and, therefore substitutable where permitted by the prescriber. They are further divided as follows:

a. AA: ingredients and dosage forms presenting neither actual nor potential bioequivalence problems (e.g., oral solutions). Some dosage forms are assigned specific codes based on criteria used to demonstrate bioequivalence.

b. AN=aerosolized drugs, AO=injectable oil solutions, AP=injectable aqueous solutions, AT=topical products.

[7] B-rated drugs are not at issue here.

c. **AB rated Drugs**: actual or potential bioequivalence problems have been resolved through adequate in vivo and/or in vitro testing.

57. AB rated generic drugs signify that they are interchangeable with the brand drug and the manufacturers of the generic drug have adequately fulfilled the requirements as set forth by the FDA for approval.

58. AB rated generic drugs are identical versions of the RLD brand drugs in terms of the following: pharmacokinetic and pharmacodynamic properties, mechanism of action, efficacy, safety, dosage, strength, intended usage, and route of administration.

59. To be considered by a P&T Committee, a generic drug medication must have an approved ANDA and have an AB therapeutic equivalence code assigned to the medication that allows it to be considered substitutable.

60. TE codes followed by numbers: applied when there are two or more drug products containing the same ingredient, with the same strength and dosage form, which are not bioequivalent to each other. In such instances, there will be more than one RLD and any generic seeking approval must prove bioequivalence to one particular RLD.

61. For generic drugs, FDA guidance is that the product is considered therapeutically equivalent to the RLD as the requirements for ANDA approval overlap with the data the agency would need to determine therapeutic equivalence.

62. Therapeutic Equivalence is the most important concept in the Orange Book. TE codes indicate substitutability between products.

**b. Entry Into the Orange Book**

63. In seeking approval for a brand drug through an NDA, manufacturer applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book.

64. A generic drug manufacturer submits an ANDA application to the FDA for approval of a generic equivalent of a drug listed in the Orange Book or 505(b)(2) NDA referencing a drug listed in the Orange Book.

65. Any generic drug manufacturer who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or 505(b)(2) NDA referencing a drug listed in the Orange Book, must certify to the FDA, for each patent listed in the Orange Book for the referenced drug, that:

a. No patent information on the drug product that is the subject of the application has been submitted to the FDA;

b. Such patent has expired;

c. The date on which such patent expires or;

d. Such patent is invalid or will not be infringed upon by the manufacturer, use or sale of the drug product for which the application is submitted.

66. The generic drug manufacturer is responsible for the accuracy of all information submitted on the ANDA and for following the process established by the FDA for their drugs to be considered for approval and subsequently considered for coverage on a drug formulary.

67. Generic drug manufacturers have to comply with certain FDA requirements to receive ANDA approval, which includes ensuring that their medications are safe and effective.

68. When an ANDA is approved, it is understood in the industry to mean that the manufacturer has fulfilled the FDA's requirements, including those of safety and effectiveness, for generic drug approval.

69. Once an ANDA is approved, the corresponding medication is listed in the Orange Book.

## VIII. General Factors that P&T Committees Consider When Placing a Drug on the Formulary

70. P&T committees consider multiple factors and sources of information when deciding to place a drug on a formulary, some of which are listed below:[8]

[8] https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/formulary-management

a. Medical and clinical literature including clinical trials and treatment guidelines, comparative effectiveness reports, pharmacoeconomic studies and outcomes data;

b. FDA-approved prescribing information and related FDA information including safety data (this will come from the ANDA which includes the information provided by the manufacturer);

c. Relevant information on use of medications by patients and experience with specific medications;

d. Current therapeutic use and access guidelines and the need for revised or new guidelines;

e. Economic data, such as total health care costs, including drug costs;

f. Drug and other health care cost data (not all P&T committees review drug specific economic data); and

g. Health care provider recommendations.

71. Included in the medical literature and FDA prescribing information that P&T Committees consider is the Orange Book, Prescription drug labels, Medication Guides, and Package Inserts.

72. P&T committees compare medications by therapeutic classifications or upon similarities in clinical use.

73. When two or more drugs produce similar effectiveness and safety results in patients, then business elements like cost, supplier services, ease of delivery or other unique properties of the agents are considered when determining which drug to include on the formulary.

74. In many organizations, the P&T committee only performs clinical analyses; if two or more medications are determined to be clinically equivalent, then business elements will determine formulary inclusion or exclusion.

75. The overall goal is to develop a list of the safest, most effective medications that will produce the desired goals of therapy at the most reasonable cost to the health care system.

**a. Materials and Representations that TPPs Rely On in Making Formulary Decisions for Generic Drugs**

76. A generic drug is a copy of a branded drug in terms of dosage, administration, and performance. Generic drugs must be equivalent to the branded drug, meaning that in addition to having the same rate and extent of drug absorption, generic drugs must be the same as that of the name brand drug, be effective against the condition or illness being treated and be as safe and otherwise equivalent to the brand name drugs.

77. Substitution of generic equivalents are encouraged by PBMs to provide the best care at an affordable cost. Some states require pharmacies to substitute generics unless otherwise prescribed by the physician.

78. Use of generic drugs that have been deemed bioequivalent by the FDA does not require a full new round of review or approval by a P&T committee, because the TPPs and P&T Committees expressly rely upon the manufacturers' compliance with all applicable standards, obligations, and regulations.

79. P&T committees will only consider adding a generic drug to their formulary if it is listed in the Orange Book and the Orange Book indicates the generic drug is the same as the RLD.

80. **A drug's "AB" listing in the Orange Book, based as it is on the generic drug manufacturer's ANDA, represents a manufacturer's assurance to TPPs and P&T Committees that the generic drug is equivalent to the brand drug for placement on a prescription drug formulary.**[9]

81. I have reviewed the formularies for EmblemHealth and SummaCare for years 2013 through 2021 and they contain VCDs in brand and/or generic. Here, the VCDs were AB rated in the Orange Book, which represented the manufacturer's assurance to TPPs and P&T Committees that the VCDs were equivalent to the brand drugs for placement on a prescription drug formulary.

[9] https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/gdl-pharmacy-therapeutics-committee-formulary-system.ashx.

82. TPPs rely on a manufacturer's compliance with all applicable standards, obligations, and regulations when referencing the Orange Book.

83. TPPs rely on manufacturers to comply with all applicable standards, obligations, and regulations and provide accurate information certifying such in their ANDA submitted to the FDA.

84. By submitting an ANDA and receiving approval, a manufacturer assures that their drug is safe and effective and the same as the referenced drug product.

85. It is industry practice that a drug must be safe in order to gain approval by the FDA and a listing in the Orange Book is an important source which by design is relied on throughout the pharmaceutical industry.

86. A generic drug product is legal in the United States if it has an ANDA approved by the FDA. A generic drug that is not ANDA approved would be illegal to sell in the United States.

87. Approved generic drugs are required to be bioequivalent and therapeutically equivalent to their brand name counterparts.

88. Bioequivalent drugs contain the same amount of active ingredient in the same dosage form, but may differ in characteristics such as shape and color. They have the same drug, dosage and form with similar bioavailability (i.e., the same amount of medication is delivered to the body over the same time period).

89. When the FDA approves a drug, it is deemed to be safe and effective to use.

90. For generics, FDA approval means that a drug is not only deemed to be safe and effective but also bioequivalent.

91. In order to obtain FDA approval of a generic drug as an Orange Book listed drug, a manufacturer is required to demonstrate that its generic drug is bioequivalent to the RLD.

92. **Products determined to be bioequivalent are included in the FDA's Orange Book so that third party payers can treat the products as therapeutic equivalent products.**

93. Therapeutic equivalent products are approved as safe and effective by the FDA.

94. Therapeutic equivalents are pharmaceutical equivalents and are expected to have the same clinical effect and safety profile. This includes meeting compendial standards (USP) for strength, quality, purity and identity and manufactured in compliance with GMP regulations.

95. Bioequivalent products are "AB" rated in the Approved Drug Products with Therapeutic Equivalence Evaluations book more commonly known as the "Orange Book."

96. Manufacturers are responsible for understanding their processes which includes preventing the presence of unacceptable contaminants or impurities, meaning any substance that does not belong in the medication.

97. Manufacturers are responsible for developing and using suitable methods to detect and limit unacceptable impurities, including any new impurities that may arise when they make changes to their manufacturing processes.

98. Maintaining equivalence to the RLD is an ongoing requirement.

99. P&T committees and TPPs rely on an Orange Book listing that a manufacturer's compliance means their drugs meet FDA regulations and as such are suitable for formulary placement and reimbursable under a prescription drug benefit plan.

100. When determining whether to place a generic drug on its formulary, a P&T committee will refer to the Orange Book's substitutability rating. One a drug has been rated as substitutable, it can be considered for the formulary.

101. A substitutable medication is approved by the FDA to be safe and effective.

102. When third party payors agree to reimburse for generic drugs such as valsartan including VCDs, they do so based on representations made by manufacturers that their drug product is in compliance with the FDA, bioequivalent of the Orange Book reference drug and safe to be sold to consumers.

103. In the case of valsartan, including VCDs, the representations made by the manufacturers were false. As such, TPPs paid for medications they should not have paid for. In fact, these VCDs never could have been sold in the United States.

104. TPPs are entitled to rely on a manufacturer's compliance with Orange Book standards when reimbursing for what was represented as generic valsartan, including VCDs.

105. The presence of the contaminants rendered the manufacturer defendants' versions of VCDs unsafe and not the same as the branded product as indicated in the Orange Book which serves as the source of truth for substitutability.

106. The contaminants were not in the RLD, and therefore the generic products could not have been equivalent to the RLD due to the presence of contaminants within the generic product.

107. Any changes to a generic drug product from the RLD are required to be reported to the FDA.

108. The contaminated VCDs were inconsistent with the ANDAs submitted for approval.

## IX. The Package Insert

109. The Package Insert ("PI"), also known as the "prescribing information," is a resource that is often the starting point for information about a particular drug.

110. In 1966, the Fair Packaging and Labeling Act required consumer product labels to be truthful and informative, with the FDA enforcing these provisions on foods, drugs, cosmetics and medical devices.

111. Manufacturers have a duty to provide prescribing physicians with accurate information about the proper use and risks of prescription drug products so that the prescribers are better equipped to educate consumers/patients about the drug's use and risks.

112. The information included in the Package Insert must be supported by substantial evidence.

113. This data and supporting data are provided to the FDA by the manufacturer as part of the application process.

114. The current Package Insert format contains two main components: the highlights of prescribing information (HPI) and the full prescribing information (FPI).

115. The full prescribing information ("FPI") is where prescribers can find all the information needed to use the drug safely and effectively.

116. The contents of the Full Prescribing Information of the Package Insert are as follows:[10]

a. Boxed warning;
b. Indications and usage;
c. Dosage and administration;
d. Dosage forms and strengths;
e. Contraindications;
f. Warnings and precautions;
g. Adverse reactions;
h. Drug interactions;
i. Use in specific populations;
j. Drug abuse and dependence;
k. Overdosage;
l. Description (dosage form(s), ingredients, pharmacologic or therapeutic class, and other relevant information);
m. Clinical pharmacology (mechanism of action, pharmacodynamics and pharmacokinetics);
n. Nonclinical toxicology (carcinogenesis, mutagenesis, impairment of fertility, animal toxicology and/or pharmacology);
o. Clinical studies;
p. References;
q. How supplied/storage and handling; and,
r. Patient counseling information.

117. According to the FDA, a generic drug must maintain the same labeling as the RLD throughout the life cycle of the generic drug product.

118. The Code of Federal Regulation, Title 21, mandates that Package Inserts be included with packages of prescription drugs.

119. Information for Package Inserts is supplied by the Drug Manufacturer.

[10] (1-13): Nathan, J, Vider, E – The Package Insert, US Pharm; 2015;40(5):8-10, www.uspharmacist.com/article/the-package-insert. Accessed October 13, 2022.

120. The Description portion of the Package Insert contains all the ingredients the medication consists of, both active and inactive ingredients.

121. The ingredients in this section are comprehensive and must list all the ingredients within the medication.

122. Package Inserts may be accessed on the manufacturer's website.

123. Package Inserts may also be obtained through the FDA's website.

124. For generic drugs, the manufacturer website will link to the Package Insert for that particular drug.

125. Professional drug-information resources such as Micromedex Solutions and Clinical Pharmacology use the Package Insert as the source of information for monograph content.

126. Pharmacies will source information from professional drug information resources to create their patient material that accompanies the prescription drug at the point of sale.

## X. The Prescription Label

127. The following information must be on every prescription label: [11]

a. Name and address of the dispensing pharmacy;
b. Serial number of the prescription;
c. Date of the prescription;
d. Name of the prescriber;
e. Name of the patient;
f. Name and strength of the drug;
g. The generic name of the drug, even if the generic drug is unavailable to dispense or even if the substitution of a generic drug is not authorized;
h. Directions for use;
i. Appropriate cautionary statements;
j. "Filled by" or "dispensed by" with the name of the dispensing pharmacist. The name must include, at a minimum, the first initial and full last name of the dispensing pharmacist;

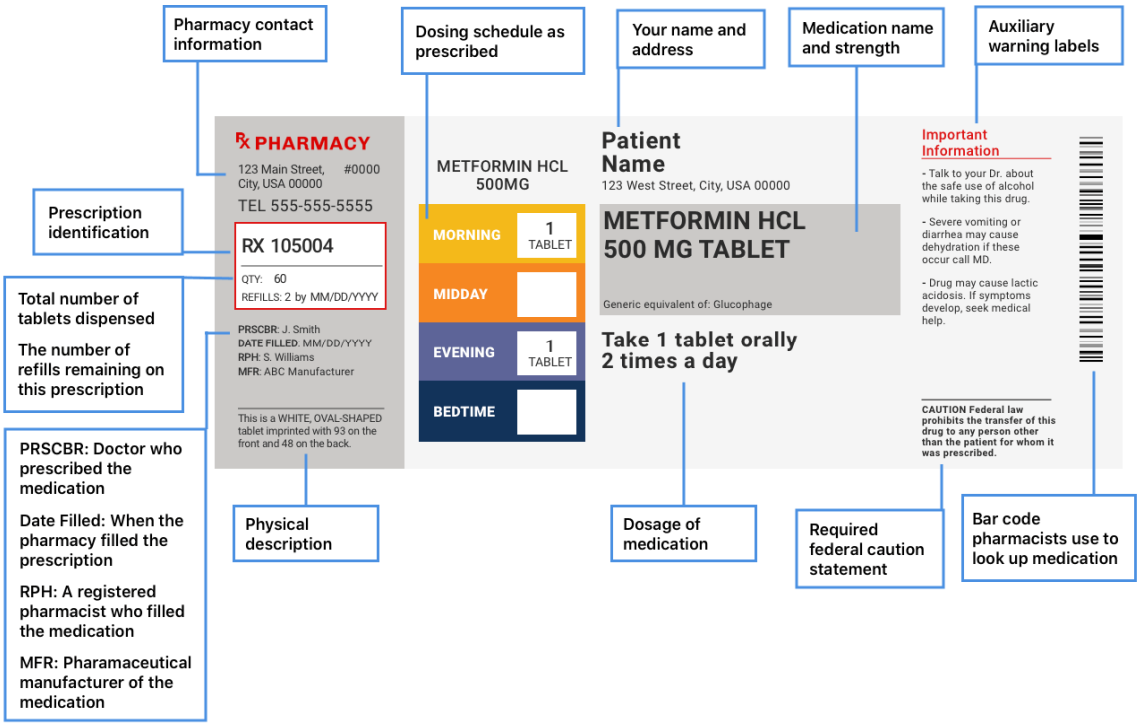
[11] http://www.ncbop.org/faqs/pharmacist/faq_inforequiredrxlabel.htm

k. If the dispensed drug is a "tranquilizer or sedative," it should bear the warning "The consumption of alcoholic beverages while on this medication can be harmful to your health" if the prescriber so directs on the prescription;

l. If the prescription is dispensed in a container other than the manufacturer's original container, a discard date, which shall be the earlier of one year from the date dispensed or the manufacturer's expiration date, whichever is earlier; and,

m. If the prescription is dispensed in the manufacturer's original container, the label must not obscure the expiration date and storage statement when the product is dispensed in the manufacturer's original container.

128. The following demonstrative is an example of a prescription drug label. Labels may vary by dispensing pharmacy:



## XI. The Medication Guide

129. Medication Guides are developed by applicants, approved by FDA, and required to be distributed to patients.[12]

130. According to the Federal Regulations for Medication Guides 208.24: "The manufacturer of a drug product for which a Medication Guide is required under this part shall obtain FDA approval of the Medication Guide before the Medication Guide may be distributed."[13]

131. A Medication Guide is required to list all of a medication's active and inactive ingredients.

132. The following is a demonstrative of an example Medication Guide template:

[12] https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/patient-labeling-resources#inserts

[13] https://www.ecfr.gov/current/title-21/part-208

**MEDICATION GUIDE**
**DRUG-X [drug X]**
**(drugimab-cznm)**
**injection, for intramuscular use**

| |
|---|
| **What is the most important information I should know about DRUG-X?**<br>… |
| **What is DRUG-X?**<br>… |
| **Who should not take DRUG-X?**<br>… |
| **Before taking DRUG-X, tell your healthcare provider about all of your medical conditions, including if you:**<br>… |
| **How should I take DRUG-X?**<br>… |
| **What should I avoid while taking DRUG-X?**<br>… |
| **What are the possible side effects of DRUG-X?**<br>…<br>Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. |
| **How should I store DRUG-X?**<br>… |
| **General information about the safe and effective use of DRUG-X.**<br>Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DRUG-X for a condition for which it was not prescribed. Do not give DRUG-X to other people, even if they have the same symptoms that you have. It may harm them.<br><br>You can ask your pharmacist or healthcare provider for information about DRUG-X that is written for health professionals. |
| **What are the ingredients in DRUG-X?**<br>Active ingredients:<br>Inactive ingredients: |
| Manufactured for:<br>Manufactured by: |

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: MM/YYYY

133. The manufacturers of the VCDs did not indicate that NDMA or NDEA were in their products in the package insert, in the medication guide, or on the prescription label. This represents a misrepresentation of their product and a deviation from current Good Manufacturing Practices.

## XII. Summary of Opinions

I. The safety of a medication must be proven by the manufacturer to the FDA so that the medication may receive approval. This information serves as an assurance that the medication meets the quality standards outlined by FDA.

II. The presence of the carcinogenic contaminants was a clear and significant deviation from the required manufacturer compliance and obligation to safety.

III. Manufacturers have ultimate responsibility for their quality process, manufacturing practices, safety obligations and all of the information presented in the ANDA which is reported to the FDA to obtain approval.

IV. If the generic manufacturer product changes in any way from the original product on the ANDA approval, then this changed product is not the same as the brand name medication (RLD).

V. The generic drug label, insert, and pamphlets are no longer accurate insofar as the generic manufacturers are not meeting the obligations required by the regulations; the changed product cannot be deemed safe or effective and equivalence is nulled; and the generic manufacturer may no longer rely on the RLD.

VI. TPPs, PBMs and P&T committees rely on the FDA approval as the indicator that the medication may be considered for formulary placement and plan coverage/reimbursement.

VII. The Orange Book lists the FDA approved generics of the original brands. The pharmaceutical industry, including TPPs, are meant to be able, by design, to rely on the information in the Orange Book such that these FDA approved generics can be put on a prescription drug formulary and/or plan coverage for reimbursement.

VIII. The TPPs in this matter were all payors at risk for and made payments in connection with their insureds' purchases of VCDs.

IX. PBMs establish formularies for generics based on the FDA approval process, and the information within the Orange Book tying these generics to their RLDs with the expectation that they are the same and/or therapeutically equivalent to the RLDs. TPPs reimbursed for these VCDs based on the assurances provided by the manufacturer in seeking approval and marketing the generics under the approved ANDA.

X. The assurances from the manufacturers of these products turned out to be false. TPPs paid for medications that they should not have based on the manufacturers' false

representations. TPPs would not have selected these products for inclusion on their drug formularies or paid for these medications if they were aware of the potential presence of contaminants within the products

XI. TPPs would not have paid for medications if they were not deemed safe and effective by the FDA.

XII. An ANDA would not have been issued if the presence of the contaminant was known because the presence of the contaminant would have been inconsistent in ingredients to the RLD and thus would not receive approval by the FDA.

XIII. Responsibility lies with the manufacturers to be fully aware their medication consisting of carcinogenic contaminants was being sold to millions of consumers.

XIV. In my professional opinion, the manufacturers' assurances as to these VCDs were false. The TPPs unjustly paid for medications for which they should not have paid. Manufacturers are accountable for the false assurances and representation of their drug products as equivalent to their RLDs.

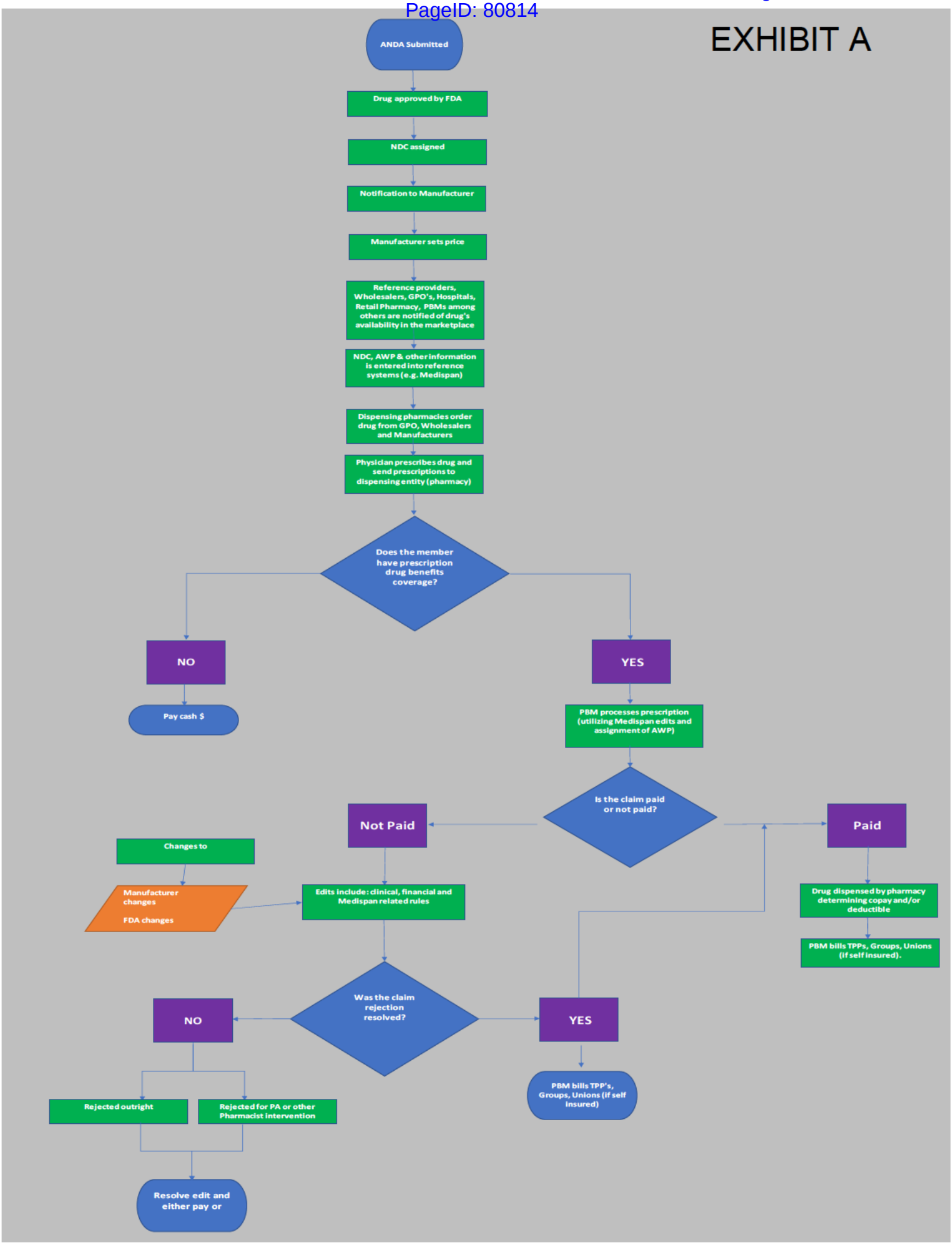
The foregoing opinions are a true and correct statement of my opinions to the best of my knowledge, information and belief under penalty of perjury.

October 31, 2022

*Kali Panagos*

Kali Panagos, Pharm.D., R.Ph.

# EXHIBIT A


ANDA Submitted
Drug approved by FDA
NDC assigned
Notification to Manufacturer
Manufacturer sets price
Reference providers, Wholesalers, GPO's, Hospitals, Retail Pharmacy, PBMs among others are notified of drug's availability in the marketplace
NDC, AWP & other information is entered into reference systems (e.g. Medispan)
Dispensing pharmacies order drug from GPO, Wholesalers and Manufacturers
Physician prescribes drug and send prescriptions to dispensing entity (pharmacy)
Does the member have prescription drug benefits coverage?
NO
Pay cash $
YES
PBM processes prescription (utilizing Medispan edits and assignment of AWP)
Is the claim paid or not paid?
Not Paid
Changes to
Manufacturer changes
FDA changes
Edits include: clinical, financial and Medispan related rules
Was the claim rejection resolved?
NO
Rejected outright
Rejected for PA or other Pharmacist intervention
Resolve edit and either pay or
YES
PBM bills TPP's, Groups, Unions (if self insured)
Paid
Drug dispensed by pharmacy determining copay and/or deductible
PBM bills TPPs, Groups, Unions (if self insured).

**APPENDIX A TO EXPERT REPORT OF KALI PANAGOS, PHARM.D., R.PH.**

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[redacted]

[redacted]

[redacted]

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# Appendix B

Kaliopi Panagos CV

# Kaliopi Panagos, Pharm.D., R.Ph., B.S.

## Healthcare-Pharmacy-Managed Care Leader

Current Residence: Bayside, New York | 917-309-7398 | k.panagos@gmail.com
Linkedin: https://www.linkedin.com/in/kali-panagos-9069ba9/

### Executive Overview

**Dynamic, hands-on leader with over twenty years of experience. Supportive, persuasive and tenacious with a focused ability to empower teams to deliver the highest quality in the areas of overall PBM operations, clinical development and client/account/member services. Highly effective at driving growth, increasing efficiency, maximizing client satisfaction while achieving positive business results. Solid communication and interpersonal skills with superior expertise in overall PBM operations, strategy, design and execution of market competitive programs and clinical offerings rooted in integrity.**

### Key Strengths

- ✓ Problem Solving /Critical Thinking
- ✓ PBM Expertise/Resource allocation
- ✓ Adaptable/Emotional Intelligence
- ✓ Process improvement/Team Engagement
- ✓ Accountable/Results Driven/Responsible
- ✓ Organized/Creative/Innovative

### Professional Experience

ARMSRx Pharmacy Benefit Consulting, LLC
*Executive Vice President, ARMSRx* *5/2021-present*
*Senior Vice President, Clinical and Consulting* *2/2019-4/2021*

AristaRx Wellness, LLC, New York, NY
*Principal & Founder – Pharmacy Benefit Consultant* *2018-present*

Council of Strategic Healthcare Advisors
*Current Panel Advisors-Managed Care Expert* *2018*

SmithRx, San Francisco, CA
*Director of Clinical Services* *2018*
Very early-stage start-up pharmacy benefit administrator – Series A Funding. Lead clinical development, strategy and process. Also supported hiring process, training and sales support. Implemented multiple workflow process improvements and provided guidance for growth with an emphasis on strong, trusting client relationships.

- Clinical Expertise: Meaningful Clinical Interventions resulted in over $100,000 in savings

Broadreach Medical Resources, Inc, New York, NY
(Prescription Benefits Administrator)
*Clinical Pharmacist/Director of Clinical Operations/Head of Client Services & Account Management* *2008-2018*
Privately held Pharmacy Benefit Administrator. Joined company early stages of development and quickly took on a broad scope of responsibility. Boosted revenue for company through meticulously developed and managed clinical programs, continual member support team education, training and management and product innovation.

Highlights include:

- Established, built and maintained trusting, positive, professional relationships at all decision levels within managed care client base
    - ~150,000 total lives (includes self-insured Labor, Hospital Sector, Commercial plans, Reference Based Program, Discount Card & MedicareD EGWP)
- Developed industry exclusive prescription indemnity/reference based program
- Designed evidence based, market competitive clinical programs with documented ROI
- Managed integration of data across medical and prescription including Population Health & Enrollment Analytics
- Served as subject matter expert on all PBM, clinical, drug and specialty items
- Managed vendor/partner relationships including Claim Adjudication platform, specialty & mail
- Implemented audit programs to ensure clinical and financial validity

Long Island University College of Pharmacy, Brooklyn, NY
*Director of Pharmacy Academic Services* *2002-2006*
*Adjunct Assistant Professor of Pharmacy, Division of Social & Administrative Sciences* *2004-2009*

- Responsible for measurement of student achievement and curriculum performance
- Implemented a comprehensive program of assessment for the purpose of programmatic improvements in accordance with the Accreditation Council for Pharmacy Education (ACPE) accreditation requirements for the College of Pharmacy
- Advised/co-chaired various committees including: assessment, academic, faculty and administration to implement and review effective strategies for assessment of student learning on all levels
- Managed team of four academic advisors and three support personnel

Walgreen's Pharmacy, New York, NY
*Immunizing & MTM Pharmacist (full-time/part-time/per-diem)* *2000-2015*

- Lead pharmacist in highest RX volume store in NYC district (>600 RX/day)
- Expert counseling on prescriptions and OTC, Nutritional, Vitamins and Holistic therapies
- Managed and trained pharmacy interns & technicians

NYS Board of Pharmacy, New York, NY
*State Board Exam Compounding Proctor & Grader* *2002-2009*

- Exam supervisor, facilitator and evaluator for accuracy

## Education

***NYS Pharmacist License 470480***

DOCTOR OF PHARMACY, Shenandoah University (1/2006)
BACHELOR OF SCIENCE-PHARMACY, St. John's University (1/2000)
BACHELOR OF SCIENCE- BIOLOGY Minor: COMPUTER SCIENCE, St. John's University (5/1997)
NYS Office of the Professions Additional Qualification – Immunization Certified
American Heart Association BLS+CPR Certified (Adult, Child, Infant)
Outcomes MTM Medication Therapy Management Trained
NYS Department of Financial Services Independent Adjuster License Producer

## Professional Organizations

AMERICAN COLLEGE OF HEALTHCARE EXECUTIVES (ACHE)
ACADEMY OF MANAGED CARE PHARMACY (AMCP)

WOMEN LEADING HEALTHCARE MEMBER (WBL)
HEALTHCARE BUSINESSWOMEN'S ASSOCIATION (HBA)
AMERICAN ASSOSCIATION OF CONSULTANT PHARMACISTS (ASCP)
AMERICAN SOCIETY OF HEALTH SYSTEM PHARMACISTS (ASHP)

## Clinical Affiliations

NYU – BELLEVUE MEDICAL CENTER, NEW YORK, NEW YORK
Lipid, Cardiovascular & Anticoagulation Focus

NORTHWELL HEALTH UNIVERSITY, MANHASSET, NEW YORK
Diabetes & Internal Medicine Focus

HOSPITAL FOR SPECIAL SURGERY, NEW YORK, NEW YORK
Anesthesiology & Pain Management Focus

Advisory Panel Member – AMGEN for Repatha